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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,108	06/07/2001	Winthrop D. Childers	10008114-1	2356

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EXAMINER
TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No. 09/878,108	Applicant(s) CHILDERS, WINTHROP D.	
	Examiner My-Chau T. Tran	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *11-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 June 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (Claims 1-10) in Paper No. 6 is acknowledged.

2. Claims 11-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: In figure 3, reference numbers 28', 28'', and 99. In figure 5A, reference numbers 22, 60', 56, 50, and 42. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

4. Claims 1-10 are treated on the merit in this Office Action.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The instant claim recites the defined volume of the substance containing cellular material comprises a plurality of individual volume, wherein each individual volume is between about 1 and about 500 picoliters and wherein characteristics of the substances containing cellular material may vary from individual volume to individual volume in a known predetermined manner.

The specification disclosure does not sufficiently teach that the defined volume would contains a plurality of individual volume, wherein each individual volume is between about 1 and about 500 picoliters and wherein characteristics of the substances containing cellular material may vary from individual volume to individual volume.

The specification description is directed to the biological sample to be studied may be present on the receiving apparatus as a single droplet or may be present as a series or array of discrete droplets or units (pg. 9, lines 9-11). Therefore, the specification does not teach that the defined volume would contains a plurality of individual volume, wherein each individual volume is between about 1 and about 500 picoliters and wherein characteristics of the substances containing cellular material may vary from individual volume to individual volume in a known predetermined manner.

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.,* 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel,* 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)].

In this present instance, the specification disclosure clearly does not teach the scope of the defined volume, which would include a defined volume that contains a plurality of individual volume, wherein each individual volume is between about 1 and about 500 picoliters and wherein characteristics of the substances containing cellular material may vary from individual volume to individual volume in a known predetermined manner.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) The phrase "capturing data" is vague and indefinite because it is unclear how data can be capture. Since data are information that can be store or collected by a computer or a mental process.

b) The phrase "known predetermined manner" is vague and indefinite because it is unclear to what "predetermined manner" is it referring to. Is it the method of measuring each individual components of a cell? Or is it the method of measuring the volume of solution?

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Stylli et al. (US Patent 5,985,214).

Stylli et al. teaches an automated method and system for identifying chemicals having useful activity such as biological activities of chemicals and collecting informations resulting from such a process (col. 6, lines 1-24). The method comprise of testing a therapeutic chemical for modulating activity of a target such as cell surface proteins in a cell based assay (col. 38, lines 46-67; col. 39, lines 1-9). The method comprise of dispensing the reagents (pharmaceutical active agent) into the addressable sample wells, which contains a predetermined volume of the sample (cellular material) (col. 6, lines 25-40; col. 8, lines 14-18) (referring to claim 1). The electrically sensitive volume displacement unit can dispense a predetermined volume of 500 to 1 picoliter (col. 16, lines 39-44) (referring to claim 4). The wells are arranged in a two dimensional array such as a 96 well plate (col. 15, lines 42-44) (referring to claims 8-9). The

method includes storing, managing, and retrieving data collected from the assay process (col. 29, lines 14-26) (referring to claim 1). The automated method can comprise of multiple dispensers for dispensing different reagents in a complex screening process (col. 33, lines 32-48) (referring to claim 10). Therefore, Stylli et al. anticipate the presently claimed invention.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balch (US Patent 6,083,763) in view of Stylli et al. (US Patent 5,985,214).

Balch discloses a method of drug screening in a 96-well sample plate (fig. 17; col. 9, lines 11-13). The drug reacts with biosite (cellular material) in the 96-well sample plate. The

biosites comprise of biological molecules that are deposited on the top surface of the substrate (col. 9, lines 24-26). The 96-well sample plate is scanned by a scanning mechanism to produce an image (capturing data).

The method of Balch does not expressly disclose that the drug is dispensed onto the cellular material.

Stylli et al. teaches an automated method and system for identifying chemicals having useful activity such as biological activities of chemicals and collecting informations resulting from such a process (col. 6, lines 1-24). The method comprise of testing a therapeutic chemical for modulating activity of a target such as cell surface proteins in a cell based assay (col. 38, lines 46-67; col. 39, lines 1-9). The method comprise of dispensing the reagents (pharmaceutical active agent) into the addressable sample wells, which contains a predetermined volume of the sample (cellular material) (col. 6, lines 25-40; col. 8, lines 14-18) (referring to claim 1). The electrically sensitive volume displacement unit can dispense a predetermined volume of 500 to 1 picoliter (col. 16, lines 39-44) (referring to claim 4). The wells are arranged in a two dimensional array such as a 96 well plate (col. 15, lines 42-44) (referring to claims 8-9). The method includes storing, managing, and retrieving data collected from the assay process (col. 29, lines 14-26) (referring to claim 1). The method of Stylli et al. would provide the advantage of reducing the volume of sample processes and consumable cost (col. 9, lines 7-15).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the method of dispensing drug onto the cellular material as taught by Stylli et al. in the method of Balch. One of ordinary skill in the art would have been motivated to include the method of dispensing drug onto the cellular material in the method of

Balch for the advantage of providing a reduction in the volume of sample processes and consumable cost (Stylli: col. 9, lines 7-15). Since both Balch and Stylli et al. disclose an assay format in a 96-well plate (Balch: fig. 17; col. 9, lines 11-13; Stylli: col. 15, lines 42-44).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
January 9, 2003

PADMASHRI PONNALURI
PRIMARY EXAMINER